STATE OF IOWA ex rel. THOMAS J. MILLER, ATTORNEY GENERAL OF IOWA 99AG25112)	EQUITY NO). <u>CE</u>	602	<u>5</u> 0
ELI LILLY A	Plaintiff, v. ND COMPANY,)	PETITION	e E	8	P
	Defendant.)			87 -7	
	INTRODUCTIO	Ŋ			ç, Ç	

The State of Iowa ex rel. Attorney General Thomas J. Miller, through Special Assistant Attorney General William L. Brauch and Assistant Attorney General Robert H. Meyers, pursuant to the provisions of Iowa Code § 714.16 (2007), states as follows for its cause of action against defendant ELI LILLY AND COMPANY:

JURISDICTION AND VENUE

- 1. This action is brought by the State of Iowa ex. rel. Attorney General Thomas J. Miller, which has jurisdiction to bring this action pursuant to Iowa Code § 714.16.
- 2. Defendant ELI LILLY AND COMPANY ("Lilly" or "Defendant") at all times mentioned herein transacted business in Polk County and elsewhere within the State of Iowa by advertising, soliciting, selling, promoting and distributing prescription drugs, including Zyprexa®. The State of Iowa invokes the jurisdiction of this Court pursuant to the provisions of Iowa Code § 714.16. The violations of law described herein have occurred in Polk County and

elsewhere in the State of Iowa. Venue is proper in Polk County pursuant to the provisions of Iowa Code § 714.16(10).

PARTIES

- 3. Plaintiff, the State of Iowa ex rel. Attorney General Thomas J. Miller, is charged with the enforcement of the Iowa Consumer Fraud Act, Iowa Code § 714.16.
- 4. Defendant Lilly is incorporated under the laws and statutes of the State of Indiana; its principal place of business is Lilly Corporate Center, Indianapolis, Indiana 46285. At all times material to this petition, Defendant transacted business in the State of Iowa by advertising, soliciting, selling, promoting and distributing prescription drugs, including Zyprexa®, to consumers in the State of Iowa and nationwide.

<u>BACKGROUND</u>

- 5. Zyprexa belongs to a class of drugs traditionally used to treat schizophrenia and commonly referred to as "atypical antipsychotics." When these drugs were first introduced to the market in the 1990s, it was hypothesized that they might be used as long-term treatment for schizophrenia without posing the same risks as first-generation antipsychotics. More specifically, experts thought that atypical antipsychotics would be less likely to produce extrapyramidal symptoms ("EPS") and tardive dyskinesia ("TD").
- 6. While these drugs may reduce the risk of EPS and TD associated with first-generation antipsychotics, they also produce dangerous side effects, including weight gain, hyperglycemia, diabetes, cardiovascular complications, and other severe conditions. Zyprexa has been shown to pose a high risk of weight gain, hyperglycemia, and diabetes.

DEFENDANT'S COURSE OF CONDUCT

- 7. Lilly began marketing Zyprexa to health care professionals for the treatment of schizophrenia in 1996. Since then, the Food and Drug Administration ("FDA") has approved Zyprexa for, *inter alia*, the treatment of acute mixed or manic episodes of bipolar I disorder and for maintenance treatment in bipolar disorder.
- 8. Lilly engaged in an aggressive marketing campaign called "Viva Zyprexa!" As part of that campaign, the company marketed Zyprexa for a number of uses for which it was not approved by the FDA. For example, Lilly marketed Zyprexa for pediatric use, for use at high dosage levels, for the treatment of symptoms rather than diagnosed conditions, and for the treatment and/or chemical restraint of patients suffering from dementia.
- 9. Through this Viva Zyprexa! campaign, and all of the company's efforts to promote Zyprexa for uses for which it was not approved by the FDA, Lilly misrepresented the drug's approved uses, its safety, and its effectiveness.

CAUSE OF ACTION

- 10. The allegations contained in paragraphs 1-9 are incorporated herein by reference.
- 11. The Defendant, in the course of advertising, soliciting, selling, promoting and distributing the prescription drug Zyprexa, has violated Iowa Code § 714.16 by misrepresenting that Zyprexa had characteristics, uses, benefits, and qualities that it does not have.

REQUEST FOR RELIEF

Plaintiff respectfully requests that the Court order the following relief against Defendant:

A. Pursuant to Iowa Code § 714.16(7), issue a permanent injunction prohibiting Defendant, its successors, agents, representatives, employees, and all other persons and

entities, corporate or otherwise, in active concert or participation with any of them, from engaging in the acts and omissions alleged herein to violate Iowa Code § 714.16;

- Pursuant to Iowa Code § 714.16(7), impose civil penalties upon Defendant of В. \$40,000 for each and every violation of Iowa Code § 714.16;
- C. Pursuant to Iowa Code § 714.16(11), order Defendant to pay all costs for the prosecution and investigation of this action;
 - D. Order Defendant to pay all court costs;
- E. Retain jurisdiction to enforce this order, including any injunction ordered by the Court; and
 - F. Grant such other and further relief as the Court deems equitable and proper.

Respectfully submitted.

THOMAS J. Miller Attorney General of Iowa

illiam L. Brauch # AT0001121 Special Assistant Attorney General

1305 E. Walnut Street

Des Moines, IA 50319

Telephone: 515-281-8772

Fax: 515-281-6771 e-mail: bbrauch@ag.state.ia.us

Robert H. Meyers AT0009600

Assistant Attorney General

Hoover Building, 2nd Floor 1305 E. Walnut

Des Moines, Iowa 50319

Phone: (515)281-4951 Fax: (515)281-7551

Email: <u>rmeyers@ag.state.ia.us</u>

ATTORNEYS FOR PLAINTIFF